TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
P 67314		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/012554	05.11.2004	07.11.2003

International Patent Classification (IPC) or national classification and IPC

A61 K31/00, A61 K31/47, A61 K31/519, G01 N33/50, A61 K31/405, A61 K31/192, A61 K31/517, A61 P9/00

Applicant

ERNST-MORITZ-ARNDT- UNIVERSITÄT

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/012554

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-29 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-10 received by this Authority on 31.10.2005 with letter of 31.10.2005

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets 1/3-3/3 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☒ the claims, nos. 1-11

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☒ the claims, nos. 1

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/012554

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 4-10

because:

☒ the said international application, or the said claims Nos. 4-6, 9, 10
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See Supplemental Box

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 7, 8
are so unclear that no meaningful opinion could be formed (*specify*):

See Supplemental Box

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
☐ has not been furnished
☐ does not comply with the standard

the computer readable form
☐ has not been furnished
☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/012554

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4-6	YES
	Claims	1-3, 9, 10	NO
Inventive step (IS)	Claims	4-6	YES
	Claims	1-3, 9, 10	NO
Industrial applicability (IA)	Claims	1-3	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

V.1 The documents are numbered according to their sequence in the search report (D1-D12). Unless indicated otherwise, reference is made to the passages cited in the search report.

V.2 Documents D1 and D2 disclose the use of dipyridamole for treating cardiovascular diseases such as stroke, angina pectoris and myocardial infarction.

D3 indicates that various inhibitors of blood platelet aggregation (such as ibuprofen, sulphinpyrazone and dipyridamole) reduce the risk of stroke, myocardial infarction and arterial occlusive disease.

D4 concerns the use of indomethacin for the treatment or prophylaxis of angina pectoris or myocardial infarction.

D5 reports on the cardiovascular effects of trequinsin.

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

D6 concerns the use of MRP5 inhibitors such as probenecid, sildenafil and zaprinast for increasing the level of cyclic nucleotides and therefore for treating angina pectoris or coronary diseases.

D7 reports on the effect of MK571 following myocardial infarction.

The subject matter of claims 1 to 3, 9 and 10 thus lacks novelty (PCT Article 33(2)).

The applicant should note that the discovery of a new active mechanism of a compound in treating a disease does not make already known therapeutic applications novel.

V.3 The subject matter of claims 4-6 is considered to be novel and to involve an inventive step, since none of the cited documents discloses such a screening method.

V.4 The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of claims 4-6, 9 and 10 in their present form. Patentability may also depend on the wording of the claims.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Boxes I and III

Box I
Basis of the report

I.1 The amendments submitted with the letter of 31 October 2005 introduce substantive matter which, contrary to PCT Article 34(2)(b), goes beyond the disclosure in the international application as filed. The amendments concerned relate to the amended claim 1.

In the opinion of this Authority, a negative limitation or disclaimer with no basis in the application as filed is permissible only in order to establish novelty in relation to accidental anticipation (see the PCT Guidelines, Appendix to chapter 20, A20.21[2]).

I.2 The current substantive examination is carried out as if claim 1 did not contain a disclaimer.

Box III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1 Claims 4-6, 9 and 10 relate to subject matter which, in the opinion of this Authority, falls under PCT Rule 67.1(iv). Consequently, no expert opinion has been established in respect of the

industrial applicability of the subject matter of said claims (PCT Article 34(4)(a)(i)).

III.2 Claims 7 and 8 do not meet the requirement for clarity (PCT Article 6), since they contain a combination of two different, disparate method claims.

There are two types of method claim: a) the use of an object to achieve a technical effect, and b) a method for producing a product. Part of claim 8 relates to a method of the first type, (a), and the second part to a method of the second type,(b). The part "method for producing a pharmaceutical composition" is based on the desired "effect" of the identification method, instead of introducing a specific starting material and producing a specific product.

The problem to be solved by claim 8 is that of producing a composition for treating cardiovascular diseases. The claim does not contain the technical features which are essential for solving that problem (the identities of the substances are missing). A person skilled in the art cannot define the claimed subject matter, since the substances cover potentially unlimited structural possibilities.

As a result, claims 7 and 8 fail to meet the requirement for clarity (PCT Article 6).